Remarks and Arguments

Applicants have carefully considered the Office Action dated February 14, 2006 and the references cited therein. Applicants respectfully request reexamination and reconsideration of the application.

Claims 1-21, 23, 25, 26, 28-36 are currently pending.

Claims 9, 12, 15, and 16 have been previously withdrawn.

Claims 1, 32 - 34 have been amended.

Before responding to the most recent rejections, Applicant request that the Examiner consider the following remarks. An advantage of the present invention is that the claimed apparatus enables *in vivo* imaging and pressure measurements *across* a lesion or treatment site. *In vivo,* the stent mounting location at the time of deployment is proximate the treatment site and facilitates the positioning of one of the distal ports 41, 41' on each side of the obstruction. The claimed proximal admission port fluidly couples a pressure measurement apparatus to the distal ports ports 41, 41' thereby enabling *in vivo* measurement of the pressure gradient *across* the stent mounting location (Serial No. 09/954,763; page 9, line 9 *et seq*). A spacer element, disposed between the catheter inner and out shafts, defines the shape of the fluid channel and improves flexibility by preventing kinking or collapsing of the shaft wall during placement. Another advantage of the present invention is that the claimed proximal admission port provides an ingress into the fluid channel for *in vivo* delivery of a contrast media, therapeutic agents and other fluids to the distal ports 41, 41', thereby enabling enhanced imaging *across* a lesion and treatment of the patient lumen (Serial No. 09/954,763; page 8, lines 3-14 *et seq*) across a treatment site. or treatment site

The prior art references cited by the Examiner, including Blaeser, Krivoruchko, and Fitz, when considered singularly or in combinations do not provide the disclosure of a pair of distal perfusion ports capable of being positioned on either side of a treatment site and capable of *in vivo* fluid communication with the proximal admission port. Nor do any of Blaeser, Krivoruchko, and Fitz provide the required motivation for the combination of their respective teachings.

Claims 1-8, 10-11, 13-14, 17-19, 23 and 33-36 stand rejected under 35 USC 103(a) as being unpatentable over US Patent 6,786,918, Krivoruchko et al., hereafter

Krivoruchko, already of record, in view of US Patent 6,129, 700, Fitz, already of record. The Examiner correctly notes that Krivoruchko does not include a discharge opening in the wall of the outer shift near the stent mounting location. Instead, the examiner is relying on the disclosure in Fitz, alleging that sits teaches discharge openings 54 that allow fluids to flow from fluid channel 24 to patient's lumen and, further, that, it was been obvious to an ordinary skill in the art to include discharge opening at the distal end of the outer shaft of Krivoruchko.

Applicants respectfully disagree with Examiner' analysis of the prior art, particularly the Fitz reference. Fitz does not disclose ports located both upstream and downstream of the treatment site. The Examiner will note that Fitz discloses a sheath 22 with an open distal end. There is no teaching of a port extending through the wall of the outer tubular member and distal of the stent mounting location. Fitz attempts to justify this deficiency by explaining that the disclosed ports formed in the lumen are positioned upstream of the treatment site and "vector" the flow of contrast medium to the treatment site (Fitz, column 2, lines 36- 41). Claim 1 has been amended to recite "first and second discharge openings in fluid communication with said fluid channel, the discharge openings being located proximal and distal of the stent mounting location and extending through a wall of said outer tubular member to permit fluid flow from said admission port and fluid channel to a patient's lumen" (claim 1, line 20-24). There is no teaching, suggestion or disclosure in either of Krivoruchko or Fitz of discharge openings both proximal and distal of the stent mounting location. As such, the combined teachings of Krivoruchko and Fitz would not be capable of *in vivo* imaging or pressure measurements *across* a lesion or treatment site. In light of the foregoing, applicants respectfully assert that claim 1 is patentable over the combined teachings of Krivoruchko and Fitz. Claims 2-8, 10-11, 13-14, 17-19, 23 include all of the limitations of claim 1 and are likewise believed patentable over the combined teachings of Krivoruchko and Fitz for at least the same reasons as claim 1, as well as for the merits of their own respective limitations.

Claims 33 and 34 have been amended similar to claim 1 (claim 33, line 18-22; claim 34, line 18-22) and are likewise believed patentable over the combined teachings

of Krivoruchko and Fitz for at least the same reasons as claim 1, as well as for the merits of their own respective limitations.

Claims 32 has also been amended and now recites a stent deliver system comprising "a spacer element defining a fluid exchange passageway between itself and the sheath, the fluid exchange passageway including fluid exchange openings that extend through a wall of the sheath and open to an exterior of the catheter, at least two of the fluid exchange openings being located proximal and distal of the stent mounting location, respectively, and another of the fluid exchange openings being located at the proximal end of the catheter" (claim 32, line 6-11). Accordingly, Applicants respectfully assert that claim 32 is not anticipated by Blaeser. Claim 32 is likewise believed patentable over the combined teachings of Krivoruchko and Fitz for at least the same reasons as claim 1, as well as for the merits of its own respective limitations. In addition, claim 32 is believed patentable over the combined teachings of Krivoruchko and Blaeser. In Blaeser, the multiplicity of holes 52 extending through sheath 28 of Blaeser are arranged to enhance *flexibility* of the distal tip and are positioned so closely to each other that no measurable pressure gradient could likely be detected across the stent mounting location even if at least one hole 52 was positionable on either side of the treatment site.

The examiner will further note that the discharge port 60 of Blaeser, in one embodiment, functions as a hydraulic perfusion port and is used to enable retraction or proximal advancement of sheath 28 by hydraulic actuation (Blaeser, column 5, lines 50-59). In such embodiment, the sheath 28 having a plurality of holes 52 (Blaeser, column 6, lines 9-13; Figure 4) would appear to prevent retraction or proximal advancement of sheath 28 by hydraulic actuation, as the multiplicity of holes would prevent the buildup of adequate pressure for movement of the sheath in either direction. Such embodiment would appears inoperative. Accordingly, the only embodiment in which sheath 28 with a plurality of holes 52 would appear operative is for port 60 to function as a pullback wire egress (Blaeser, column 5, lines 23-32). Such embodiment does not enable *in vivo* pressure measurements *across* a lesion or treatment site. Nor would combining the sheath 28 of Blaeser with the teachings of Krivoruchko render the claimed subject matter obvious. There is no motivation, teaching or suggestion to combine the

respective disclosures of Blaeser with the teachings of Krivoruchko. Krivoruchko does not teach, disclose, or suggest fluid discharge openings located *proximal and distal* of the stent mounting location and extending through a wall of said outer tubular member to permit fluid flow from a proximal admission port and fluid channel to a patient's lumen, as now claimed. In light of the foregoing, Applicants respectfully assert that claim 32, as well as claims 1 and 33-34 are patentable over the teachings of Krivoruchko or Blaeser, singularly or in combinations, or when combined with any other prior art of record.

Claim 25 has been amended and now recites a stent deliver system comprising "at least one spacer disposed between said inner tubular member and said outer tubular member for maintaining a spacing between said inner tubular member and said outer tubular member, said spacer longitudinally traversing a portion of said passageway" (claim 25, line 6-9). Accordingly, Applicants respectfully assert that claim 25 and its respective dependent claims are patentable over Fitz in combination with Blaeser since their combined teaching do not teach, disclose or suggest the claimed spacer element. Claim 25 and its respective dependent claims are further believed patentable over the combined teachings or Krivoruchko and Fitz for at least the same reasons as claim 1, as well as for the merits of their own respective limitations.

Applicants believe the claims are in allowable condition. A notice of allowance for this application is solicited earnestly. If the Examiner has any further questions regarding this amendment, she is invited to call Applicants' attorney at the number listed below. The Examiner is hereby authorized to charge any fees or credit any balances under 37 CFR §1.17, and 1.16 to Deposit Account No. 02-3038.

Respectfully submitted,

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